

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

<p>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION</p>	
<p>THIS DOCUMENT RELATES TO:</p> <p><i>The City of New York v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 04-CV-06054</p> <p><i>County of Albany v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0425</p> <p><i>County of Allegany v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0236</p> <p><i>County of Broome v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0456</p> <p><i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0256</p> <p><i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0423</p> <p><i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-0214</p> <p><i>County of Chemung v. Abbott Laboratories, Inc., et al.</i> W.D.N.Y. Case No. 05-CV-6744</p> <p><i>County of Chenango v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0354</p> <p><i>County of Columbia v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0867</p> <p><i>County of Cortland v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0881</p> <p><i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i> S.D.N.Y. Case No. 05-CV-6458</p> <p><i>County of Essex v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0878</p> <p><i>County of Fulton v. Abbott Laboratories, Inc., et al.</i> N.D.N.Y. Case No. 05-CV-0519</p>	<p>MDL NO. 1456 Civil Action No. 01-12257-PBS</p> <p>Judge Patti B. Saris</p> <p>PLAINTIFFS' OPPOSITION TO INDIVIDUAL MEMORANDUM OF DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND PAR PHARMACEUTICAL, INC. IN SUPPORT OF MOTION TO DISMISS</p>

County of Genesee v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-00267

County of Greene v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0474

County of Herkimer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00415

County of Jefferson v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0715

County of Lewis v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0839

County of Madison v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00714

County of Monroe v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6148

County of Nassau v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 04-CV-05126

County of Niagara v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06296

County of Oneida v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0489

County of Onondaga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0088

County of Ontario v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6373

County of Orleans v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6371

County of Putnam v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 05-CV-04740

County of Rensselaer v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-00422

County of Rockland v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-7055

County of Schuyler v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6387

County of Seneca v. Abbott Laboratories, Inc., et al.

W.D.N.Y. Case No. 05-CV-6370

County of St. Lawrence v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0479

County of Saratoga v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0478

County of Steuben v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6223

County of Suffolk v. Abbott Laboratories, Inc., et al.
E.D.N.Y. Case No. 03-CV-12257

County of Tompkins v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0397

County of Ulster v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 06-CV-0123

County of Warren v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0468

County of Washington v. Abbott Laboratories, Inc., et al.
N.D.N.Y. Case No. 05-CV-0408

County of Wayne v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06138

County of Westchester v. Abbott Laboratories, Inc., et al.
S.D.N.Y. Case No. 03-CV-6178

County of Wyoming v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-6379

County of Yates v. Abbott Laboratories, Inc., et al.
W.D.N.Y. Case No. 05-CV-06172

INTRODUCTION

Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively “Par”) assert in their Motion to Dismiss (the “MTD”) that plaintiffs have failed to meet the requirements of Fed. R. Civ. P. 9(b) for those AWP and Best Price claims to which that rule applies.¹ Par is incorrect. Plaintiffs, in the Consolidated Complaint (“CC”) allege that Par has reported intentionally false and misleading wholesale price information on which Medicaid reimbursements are based in order to market the spread with the intention of seizing market share from competitors. CC at ¶¶ 9, 12.

Payor reliance on the price information is a necessary part of the scheme. Plaintiffs allege that defendants conceal their more accurate wholesale pricing information from payors and that the necessary data to establish the “usual and customary price charged to the general public” is not readily available. CC at ¶¶ 10, 88, n.8.² Relying on the Sandoz motion, Par also argues that there is no connection between drugs on FUL and drugs reimbursed through AWP. But unmentioned by Par/Sandoz is that many of these exemplar multi-source drugs were on FUL for a short period, and were reimbursed at AWP. *See* plaintiffs’ opposition to the Sandoz motion (“Sandoz opp.”) at 4-5.

Par’s attack on plaintiffs’ fraud claims fails because, as detailed below, plaintiffs have satisfied the Court’s 9(b) requirements including by alleging fraudulent prices for the exact products at issue.

ARGUMENT

¹ Par refers to the Sandoz MTD in support for its positions regarding multi source drugs. (*See* MTD, fn. 1) Plaintiffs thus incorporate herein their opposition to the Sandoz MTD.

² Par bases its argument on misquotations of the CC and other factual errors. Par says that the CC alleges that reliance on AWP “is absolutely necessary”. MTD at 2 citing the CC at 10. That is not what the CC says. The CC states that “Reliance on AWP is a virtual necessity.” The Nassau County complaint quote is taken out of context.

I. THE CONSOLIDATED COMPLAINT ADEQUATELY ALLEGES HOW PAR'S PRICE INFLATION SCHEME DAMAGES MEDICAID AND SATISFIES FED. R. CIV. P. 9(B)

In its prior opinions, the Court ruled that Fed R. Civ. P. 9(b)'s particularity requirements are satisfied where plaintiffs provide:

- 1) [A] spread which [plaintiff possesses] a good-faith basis to calculate³ or, alternatively;
- 2) A detailed overview of the fraudulent scheme that fits the "paradigm described in the complaint." (*In re Pharmaceutical Indust. Average Wholesale Price Litig.*, 307 F.Supp.2d 196, 210 (D.Mass.,2004)(*"Pharm III"*) [internal citation omitted]); and
- 3) "[W]ith respect to each defendant, 1) the specific drug or drugs that were purchased from defendant, 2) the allegedly fraudulent AWP for each drug and 3) the name of the specific plaintiffs that purchased the drug." *Id* at 208.

The CC satisfies 9(b)'s requirements with respect to Par. The CC pleads the applicable reimbursement scheme and proffers general allegations of defendants' fraudulent conduct, detailing how defendants' (Par included) false price reporting influenced this reimbursement scheme by causing inflated AWP's and FULs to improperly and fraudulently increase the counties reimbursement payments. *See* CC at ¶ 9, 12, 85-87, 122-136. The CC supplements these general allegations with particular details of Par's fraudulent conduct (*see* CC at ¶¶ 642-654) and details the applicable AWP and the spreads between the AWP and Par's actual widely available market prices. *See* Exhibits A&B to CC; *see also* Exhibit A to Plaintiffs' Opposition to Defendants Consolidated Motion to Dismiss ("Con. Opp.").

Par does not dispute 1) that it caused inflated AWP's to be reported or 2) that these

³ In *In re Pharm. Indust. Average Wholesale Price Litig.*, No. 01-12257, 2004 WL 2387125, at *2 (D.Mass. Oct. 26, 2004)(*"Suffolk II"*), the Court held that in the absence of allegations particularizing the circumstances surrounding the price reporting, Suffolk could satisfy 9(b) by alleging a spread which for which it has "a good-faith basis". *See Id.*, ("[t]he so-called "Suffolk 13" ...insist that the allegations concerning the spread are not particular enough because ... there are no ... allegations (e.g., government investigations or the company's own internal documents) to support a claim of fraudulent pricing.... If there is a good faith basis for calculating a spread, the Court will deny the motion to dismiss".)

inflated AWP's were relied on by NY Medicaid. As explained in the CC, reimbursements for brand name drugs and for multi-source drugs without FULs, are based on AWP. *Id.* at ¶ 86-88. Thus, Par does not dispute that plaintiffs have adequately pled reliance on AWP in this context.

Rather, Par argues Plaintiffs' reliance on Par's false and inflated AWP's is unreasonable because Par also reported WACs. MTD at 2. Par's claim is essentially that the state should have known the untruthfulness of the AWP by referring to its WAC. This is a disputed factual assertion that plaintiffs will demonstrate to be false at the appropriate time. For now, suffice that Par is setting a standard of knowledge that even Par itself does not possess. Par co-authored a brief which misstated the reimbursement category of 3 of the 7 drugs it analyzed. *See Sandoz Opp.* at 4-5. Par apparently does not even know which of its own drugs are subject to the FUL or not.

Additionally, that Par may have submitted accurate WACs (which plaintiffs do not concede) is irrelevant entirely to Par's submission of intentionally false and inflated AWP's and plaintiffs' reliance. As the United States Supreme Court made crystal clear in *Heckler v. Comty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 62 (1984), "[m]en must turn square corners when they deal with the Government."

This observation has its greatest force when a private party seeks to spend the Government's money. Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law.

Id. at 63.⁴

⁴ This rule has been adopted by New York courts and is applicable to New York's Medicaid program. *See New York State Med. Transporters Ass'n, Inc. v. Perales*, 564 N.Y.S.2d 1007, 128, 131 (N.Y. 1990) (stating that "the law is clear that those who deal with the government are expected to know the law, and cannot rely on the conduct of government agents contrary to law as a basis for "manifest injustice" claims).

In any event, the CC adequately alleges reliance on Par's false pricing information. The CC alleges that Par's fraudulent prices (not just AWP's, but all prices) served as the basis for the County Medicaid Programs' reimbursements. CC at ¶643. The CC alleges that Par knew it could market the spread to increase its market share and did so. *Id.* at ¶ 645. Plaintiffs further allege each Par NDC at issue, its fraudulent AWP, and its purchase by the Counties. *See id.*, Exhibit A, at 69-73. Finally, the Counties set forth those NDCs for which the counties' investigation had already shown Par's pricing to be fraudulently misleading by listing those drugs whose AWP's exceeded transaction prices by greater than 40% in 2000. *See id.*, Exhibit B at 24.

II. PLAINTIFFS BEST PRICE/ REBATE ALLEGATIONS AGAINST PAR SATISFY FED. R. CIV. P. 9(B)

The court has provided direct guidance regarding what Counties were required to plead to satisfy Fed. R. Civ. P. 9(b) on a Best Price/Rebate claim.⁵

Par contends that the CC "1) fails to allege a best price claim with particularity because plaintiffs fail to particularize the fraud and 2) fails to allege that Par has manufactured any of the single-source and brand name innovator drugs identified in the complaints." MTD at 3. Par also says that it has "manufactured none of them", presumably referring to the innovator-single source and innovator multi-source drugs in the complaint, as only these are subject to best price reporting requirements. MTD at 3. This is incorrect. Par has manufactured several innovator multi-source drugs at issue, and it has seen these drugs in exhibit A to the CC.⁶

⁵ The court has held that 9(b) would be satisfied by pleadings which 1) tie the Best Prices claims to particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices, [and/or] 2) allege sufficient facts regarding the circumstances of the fraudulent rebate scheme with respect to each Defendant, [and/or] 3) set forth at least minimal facts with respect to (i) the allegedly fraudulent or false price reported to the state for any specific drug; or (ii) any information showing a company-wide scheme to misstate Best Prices." *See Suffolk II*, 2004 WL 2387125 at *2.

⁶ Plaintiffs allege purchasing the following 24 different innovator multi-source and innovator brand name products

III. PLAINTIFFS' BEST PRICE CLAIMS FOR SUCH DRUGS ARE ENTIRELY PROPER.

Plaintiffs do not assert Best Price claims against Par for its multi-source products, but do assert rebate claims arising out of Par's failure to comply with its Medicaid rebate obligations. Plaintiffs' allegations rely in part on the activities of the Massachusetts Attorney General ("Mass AG") who has access to Par's AMPs. Plaintiffs do not. Thus, plaintiffs allege that the Mass AG subpoenaed Par for its AMP data and subsequently concluded it had a sufficient good faith basis to bring a rebate claim based on Par's understatement of AMP. Specifically, plaintiffs allege at CC ¶¶649-651 that Par's AMPs were materially lower than the wholesale prices Par reported and that Par consequently has underpaid Medicaid rebates.

Finally, Par ignores the Court's repeated statements that evidence of government investigations concerning misconduct similar to that at issue here is entirely relevant.⁷ As discussed above, the Massachusetts investigation and subsequent litigation is directly relevant, and except for the amounts purchased, the multi-source rebate claims are nearly identical. The other investigations discussed in plaintiffs' complaint likewise concern Par's pricing misconduct. *See* CC at 647-654.

CONCLUSION

For all the foregoing reasons, Par's motion to dismiss should be denied in its entirety.

(single-source drugs are Akineton and Questran Packet, #s 21-24) in their exhibit A- 1) 00003033850, Capozide 25/15 Tablet; 2) 00003034950, Capozide 25/25 Tablet; 3) 00003038450, Capozide 50/15 Tablet; 4) 00003039050, Capozide 50/25 Tablet; 5) 00003045054, Capoten 12.5 Mg Tablet; 6) 00003045250, Capoten 25 Mg Tablet; 7) 00003045275, Capoten 25 Mg Tablet; 8) 00003048250, Capoten 50 Mg Tablet; 9) 00003048275, Capoten 50 Mg Tablet; 10) 00003048550, Capoten 100 Mg Tablet; 11) 00015944214, Questran Light Packet; 12) 00044210070, Ssd 1% Cream; 13) 00044210071, Ssd 1% Cream; 14) 00044210073, Ssd 1% Cream; 15) 00044210077, Ssd 1% Cream; 16) 00044210078, Ssd 1% Cream; 17) 00044210079, Ssd 1% Cream; 18) 00044211071, Ssd Af 1% Cream; 19) 00087058005, Questran Powder; 20) 00087058011, Questran Packet; 21) 00087944211, Questran Light Powder; 22) 00015058011, Questran Packet; 23) 00044012002, Akineton 2mg Tablet; 24) 49884069301, Akineton 2 Mg Tablet

⁷ *See Pharm III*, 307 F.Supp.2d at 208-209; *Suffolk II*, 2004 WL 2387125, at *2.

Dated: April 17, 2006.

Respectfully submitted,

**City of New York and all captioned Counties
except Nassau, by**

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